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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,742	12/29/2003	Mark Tawa	TPI-2900C3XC2	2066
23557 7590 01/02/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER				
LAU, JONATHAN S				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/747,742

Applicant(s)

TAWA ET AL.

Examiner

Jonathan S. Lau

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 26-29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 26-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI-108)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 19 Sep 2008, in which claims 7 and 26 are amended to change the scope and breadth of the claim and new claim 32 is added.

This application is a domestic application, filed 29 Dec 2003; and claims benefit of 60/486,713 07/11/2003 and claims benefit of 60/459,501 04/01/2003 and claims benefit of 60/456,608 03/21/2003 and claims benefit of 60/456,027 03/18/2003 and claims benefit of 60/441,335 01/21/2003 and claims benefit of 60/437,516 12/30/2002 and is a continuation in part of 10/601,092 06/20/2003 abandoned which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said 10/601,092 06/20/2003 claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/428,515 11/22/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003. This application 10/747,742 is a CIP of PCT/US03/19574 06/20/2003 which claims benefit of 60/390,881 06/21/2002 and

claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 This application 10/747,742 is a CIP of PCT/US03/41273 12/24/2003 which is a CIP of 10/601,092 06/20/2003 ABN which claims benefit of 60/390,881 06/21/2002 and claims benefit of 60/426,275 11/14/2002 and claims benefit of 60/427,086 11/15/2002 and claims benefit of 60/429,515 11/26/2002 and claims benefit of 60/437,516 12/30/2002 and claims benefit of 60/456,027 03/18/2003 and said PCT/US03/41273 12/24/2003 is a CIP of 10/660,202 09/11/2003 which is a CIP of PCT/US03/27772 09/04/2003 which is a CIP of 10/378,956 03/03/2003 which claims benefit of 60/360,768 03/01/2002 and said PCT/US03/27772 09/04/2003 claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003 and said 10/660,202 09/11/2003 is a CIP of 10/637,829 08/08/2003 which is a DIV of 10/295,995 11/18/2002 PAT 6,699,840 and said 10/295,995 is a CON of 10/232,589 09/03/2002 PAT 6,559,293 which claims benefit of 60/406,974 08/30/2002 and claims benefit of 60/380,288 05/15/2002 and claims benefit of 60/356,764 02/15/2002 and said 10/660,202 is a CIP of 10/449,307 05/30/2003 PAT 7,078,526 which claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/444,315 01/31/2003 and claims benefit of 60/439,282 01/10/2003 and claims benefit of 60/384,152 05/31/2002 and said 10/660,202 is a CIP of 10/601,092 06/20/2003 ABN and claims benefit of 60/451,213 02/28/2003 and claims benefit of 60/463,962 04/18/2003 and claims benefit of 60/487,064 07/11/2003.

Claims 7, 26-29 and 32 are pending in the current application.

However, the parent applications 60/390,881, 60/426,275, 60/427,086 and 60/429,515 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the instant claims 7, 26-29 and 32 of this application since all parent applications are not seen to disclose the pharmaceutical composition comprising a form of a propylene glycol solvate of celecoxib in the independent claim 7. 60/390,881 discloses celecoxib sodium salt (example 1, page 28 and example 2, page 30) and celecoxib sodium salt tetrahydrate (example 3, page 30). 60/426,275 discloses celecoxib sodium salt (example 1, page 28 and example 2, page 30) and celecoxib sodium salt tetrahydrate (example 3, page 30). 60/427,086 discloses celecoxib sodium salt (example 1, page 31 and example 2, page 33) and celecoxib sodium salt tetrahydrate (example 3, page 34). 60/429,515 discloses celecoxib with propylene glycol in the form of a pharmaceutical excipient, not a solvate (page 2, lines 20-25). Written description is found in 60/437,516 disclosing celecoxib propylene glycol solvates such as examples 15-17 at pages 45-46. Thus, the filing date of the instant claims is deemed to be the filing date of 60/437,516, 30 Dec 2002. If applicant disagrees, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the earlier priority applications. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

Rejections Withdrawn

Applicant's Remarks, filed 19 Sep 2008, with respect to claims Claims 7, 26-29 and 32 rejected under 35 U.S.C. 103(a) as being unpatentable over Talley et. al. (U.S. Patent No. 5,760,068; of record) in view of Rubino et. al. (Int. J. Pharm. 65, 1990, 141-145; provided by Applicant in IDS mailed 02 Aug 2004) has been fully considered and is persuasive, as Applicant notes that Rubino et al. teaches at Table 1 that all the sulfonamide compounds tested formed crystal hydrates and not solvates with propylene glycol.

This rejection has been **withdrawn**. However, upon further consideration, a new ground(s) of rejection under 35 U.S.C. 112, first paragraph is made in view of Applicant's remarks.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 7, 26-29 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A pharmaceutical composition comprising a form of a propylene glycol solvate of celecoxib.

The state of the prior art: Rubino et al. (Int. J. Pharm. 65, 1990, 141-145; provided by Applicant in IDS mailed 02 Aug 2004) teaches that sodium salts of sulfonamides crystallized in the presence of propylene glycol and water may still crystallize in the form of hydrates (page 143, right column, paragraph 2) Rubino et al. teaches at Table 1 that all the sulfonamide compounds tested formed crystal hydrates and not solvates with propylene glycol.

Brittain (Polymorphism in Pharmaceutical Solids, 1999, p183, 202-208, 219, cited in PTO-892) discloses pharmaceutical solids that come into contact with water during processing steps such as crystallization may form hydrates (page 202, paragraph 3). Brittain discloses exposure of a crystal solvate to atmosphere containing water vapor

may result in formation of a hydrate. Brittain discloses hydrates may be obtained from the mixed solvent systems (page 204, paragraph 4). Brittain discloses a pharmaceutical compound may produce a broad scope of possible hydrate and solvate forms (page 207, paragraph 3). Brittain discloses crystallization is highly unpredictable, and requires an empirical approach (page 219, paragraph 2).

Davidovich et al. (American Pharmaceutical Review, 2004, 7(1) p10, 12, 14,16, 100, cited in PTO-892) discloses that morphology and particle shape/size can induce severe preferential organization that can degrade the utility of XRD powder data to characterize a specific crystal form, and that small changes in the X-ray powder patterns may falsely imply the presence of a new crystalline form (page 10, left column, Abstract). Davidovich et al. discloses that the highly dynamic nature of crystallization can lead to variations in crystal formation, with minor variations resulting in significant modifications of crystal form (page 12, left column, paragraph 1).

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While the reactivity of most chemical functionalities in solution is relatively predictable, the art of crystalline forms is highly unpredictable, involving poorly understood nucleation events, crystal packing forces, and the role of trace impurities. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible sample preparation technique and analytical instrument could potentially be used to characterize said form of a propylene glycol solvate of celecoxib.

The amount of direction or guidance presented: The specification speaks generally about methods of preparing solvates at page 10, paragraphs 2-3. It is suggested that propylene glycol solvates have advantageous properties at page 13, paragraph 3.

The presence or absence of working examples: The only working examples provided are for the production of a crystallized solid celecoxib produced in the presence of propylene glycol and ether at examples 1-3 in page 40-42. It is well known that ether is a highly hygroscopic solvent and absorbs moisture from the atmosphere. These crystallized solids are asserted to be solvates of propylene glycol. However, no data regarding the characterization of the chemical identity of the composition of the celecoxib propylene glycol solvates is provided beyond thermogravimetric analysis and powder X-ray diffraction. As disclosed by Davidovich et al., powder X-ray diffraction data does not necessarily identify a novel chemical composition in a new crystalline form. TGA shows the loss of 15.59% weight from celecoxib sodium propylene glycol (figure 1), 14.94% weight from celecoxib potassium propylene glycol (figure 3) and 16.29% weight from celecoxib lithium propylene glycol (figure 5). No evidence is provided to show that the matter lost from the solvate during thermogravimetric analysis is necessarily propylene glycol (76.1 g/mol). The weight lost in the TGA is also consistent with the conversion of the tetrahydrate (72 g/mol) celecoxib salt to an anhydrous celecoxib salt.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the art of crystalline forms. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible celecoxib propylene glycol solvates beyond those known in the art, one skilled in the art would undertake a novel and extensive research program into the preparation of specific solvate forms of celecoxib. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of crystallization conditions, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for any celecoxib propylene glycol solvates.

Conclusion

No claim is found to be allowable.

This Office Action details new grounds of rejection not necessitated by Applicant's Amendment. Accordingly this Office Action is Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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